



**UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION IV  
611 RYAN PLAZA DRIVE, SUITE 400  
ARLINGTON, TEXAS 76011-4005**

September 18, 2006

EA-06-035

Mark A. Smith, CHP  
Vice President, Radiation Services  
Sterigenics International, Inc.  
10811 Withers Cove Park Drive  
Charlotte, North Carolina 28278

**SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY -  
\$9,600 (NRC INSPECTION REPORT 030-36691/2004-001 AND  
INVESTIGATION REPORT 4-2005-007)**

Dear Mr. Smith:

This refers to the predecisional enforcement conference conducted on May 3, 2006, at the NRC Region IV office in Arlington, Texas. The conference was conducted to discuss three violations that were identified during an NRC inspection of one of your facilities. The inspection was conducted to determine the facility's compliance with the NRC's June 6, 2003, Order Imposing Compensatory Measures for Panoramic and Underwater Irradiator Licensees (Order). In addition, the NRC's Office of Investigations conducted an investigation into alleged deliberate misconduct related to two of the violations. The findings from the inspection and investigation were discussed with you and Mr. Michael Bula during a telephonic exit briefing on March 8, 2006, and were documented in the subject inspection report dated March 21, 2006. The inspection report contained information that was designated as Safeguards Information - Modified Handling (SGI-M), and therefore was not made publicly available. The May 3 conference was also closed to public observation because the subject matter involved investigative results that were not available to the public.

Based on the information developed during the inspection and investigation, and the information that you provided during the conference, the NRC has determined that three violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation (Notice), and the circumstances surrounding them are described in detail in the subject inspection report. The first violation involved a senior Sterigenics manager faxing over unprotected telecommunications circuits SGI-M Information to Sterigenics' security contractor, when the manager knew faxing the information was in violation of the Order. The second violation involved the senior manager providing the NRC with information that he knew was incorrect and inaccurate regarding the circumstances of the faxed document. The third violation resulted when Sterigenics failed to ensure that the contractor would adhere to Sterigenics' policies and procedures for handling this SGI-M information and also failed to make a trustworthiness and reliability determination before providing the contractor with the SGI-M information.

The significance of the first two violations was considered collectively because both violations involve willfulness, specifically the deliberate misconduct form of willfulness. In considering the

significance of the first two violations, the NRC considered: (1) the importance of the SGI-M information that was faxed over unprotected telecommunications circuits; (2) the fact the recipient did not have a need to know some of the information; (3) the significance of the inaccurate and incomplete information provided to the NRC; and (4) the level of the Sterigenics official (a senior official) who engaged in deliberate misconduct. In accordance with the NRC Enforcement Policy, the first two violations have been categorized collectively as a Severity Level II problem.

The third violation is significant because the SGI-M information was provided to a Sterigenics contractor without Sterigenics providing training to the contractor and taking steps to ensure that the contractor would adhere to policies and procedures for handling SGI-M. As a result of Sterigenics' failure, the contractor unknowingly mishandled SGI-M information by faxing the SGI-M information over unprotected telecommunications circuits. Therefore, this violation has been categorized in accordance with the NRC Enforcement Policy at Severity Level III.

In accordance with the Enforcement Policy, a base civil penalty in the amount of \$9600 is considered for a Severity Level II problem (based on the civil penalty amounts at the time of the violations.) Because of the willfulness involved and because this is a Severity Level II problem, the NRC considered whether credit was warranted for both Identification and Corrective Action in accordance with the civil penalty assessment process in Section VI.C.2 of the Enforcement Policy. The NRC determined that the licensee is not deserving of identification credit because the violations and the deliberate misconduct were identified by the NRC. However, the NRC determined that credit is warranted for Sterigenics' comprehensive Corrective Actions. Your actions included promptly investigating the circumstances of the violations, terminating the senior official's employment, conducting additional training to employees and other senior officials, conducting audits of other Sterigenics facilities for similar problems, and making improvements to internal procedures to ensure compliance with the Order. As a result of withholding Identification credit but granting Corrective Action credit, this Severity Level II problem is assessed a civil penalty in the base amount of \$9600.

With regard to the third violation, a base civil penalty in the amount of \$6000 is considered for a Severity Level III violation (based on the civil penalty amounts at the time of the violation). Because your facility has not been the subject of escalated enforcement actions within the last 2 years, the NRC considered whether credit was warranted for Corrective Action in accordance with the civil penalty assessment process in Section VI.C.2 of the Enforcement Policy (Identification credit is not considered for this non-willful Severity Level III violation). Based on Sterigenics' response to the violation, the NRC determined that Corrective Action credit was warranted. In addition to the corrective actions discussed above, Sterigenics took actions to ensure its contractors who had a need to know SGI-M have been appropriately trained on the handling procedures, that trustworthiness and reliability determinations have been conducted for all individuals (including contractors) that have access to SGI-M information, and that procedures were modified to prevent recurrence of this violation. As a result of granting Corrective Action credit, this Severity Level III violation is not assessed a civil penalty.

Therefore, to emphasize the importance of complying with the Order, of providing the NRC with complete and accurate information, and of not engaging in willful noncompliance, I have been authorized, after consultation with the Director, Office of Enforcement, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the base amount of

\$9600. In addition, issuance of this Notice constitutes escalated enforcement action, that may subject you to increased inspection effort.

In accordance with the NRC Enforcement Policy, you may request alternative dispute resolution (ADR) with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflict outside of court using a neutral third party. The technique that the NRC has decided to employ during a pilot program, which is now in effect, is mediation. Additional information concerning the NRC's pilot program is described in the enclosed brochure (NUREG/BR-0317) and can be obtained at <http://www.nrc.gov/what-we-do/regulatory/enforcement/adr.html>. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as an intake neutral. Please contact ICR at 877-733-9415 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, along with Enclosure 1, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. The NRC also includes significant enforcement actions on its Web site at [www.nrc.gov](http://www.nrc.gov); select What We Do, Enforcement, then Significant Enforcement Actions.

Sincerely,

/RA/

Bruce S. Mallett  
Regional Administrator

Docket No. 030-36691  
License No. CA 3390-30

Enclosures:

- (1) Notice of Violation and Proposed Imposition of Civil Penalty
- (2) NUREG/BR-0317 (Licensee only)
- (3) NUREG/BR-0254 Payment Methods (Licensee only)

cc (w/Enclosure 1):  
State Radiation Control Program Director

NOTICE OF VIOLATION  
AND  
PROPOSED IMPOSITION OF CIVIL PENALTY

Sterigenics International, Inc.  
Charlotte, North Carolina

Docket No. 030-36691  
License No. CA 3390-30  
EA-06-035

During an NRC inspection and investigation which concluded on March 8, 2006, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the NRC proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

I. Violations Assessed a Civil Penalty

- A. NRC's June 6, 2003, Order Imposing Compensatory Measures (Order) requires, in part, that licensees must ensure that they develop, maintain, and implement strict policies and procedures for the proper handling and unauthorized disclosure of safeguards information in accordance with the requirements in Attachment 3, "Modified Handling Requirements for the Protection of Certain Safeguards Information (SGI-M)."

Attachment 3 requires, in part, that SGI-M may not be transmitted by unprotected telecommunications circuits except under emergency or extraordinary conditions. For the purpose of this requirement, emergency or extraordinary conditions are defined as any circumstances that require immediate communications in order to report, summon assistance for, or respond to a security event (or an event that has potential security significance). This restriction applies to telephone, telegraph, teletype, facsimile circuits, and to radio.

Contrary to the above, on or about April 28, 2004, the licensee transmitted SGI-M over unprotected telecommunications circuits under conditions that were neither emergency or extraordinary. Specifically, a licensee employee faxed a document that contained SGI-M to the licensee's security contractor, for purposes of developing the contract for monitoring the intrusion detection system, a condition that was neither emergency or extraordinary.

- B. 10 CFR 30.9 requires, in part, that the information provided to the NRC by a licensee, or information required by statute or by the NRC's regulations or orders to be maintained by the licensee shall be complete and accurate in all material respects.

Contrary to the above, on October 18-19, 2004, and on March 9, 2005, a licensee employee provided NRC with information that was not complete or accurate in all material respects. Specifically, during an NRC inspection and

later during an interview by the NRC's Office of Investigations, a licensee employee stated that a "safeguards information-modified handling (SGI-M)" document was faxed from the licensee's security contractor, but the individual failed to disclose that he had first faxed the document to the contractor and asked them to sign it and fax it back. Second, the individual did not provide accurate information to an NRC investigator when the individual denied ever informing the inspectors the document had not been faxed. This was material because proper maintenance and handling of SGI-M was required by the Order.

This is a Severity Level II problem (Supplements III and VII).  
Civil Penalty - \$9600 (EA-06-035)

## II. Violation Not Assessed a Civil Penalty

NRC's June 6, 2003, Order Imposing Compensatory Measures (Order) requires, in part, that licensees must ensure that they develop, maintain, and implement strict policies and procedures for the proper handling and unauthorized disclosure of safeguards information in accordance with the requirements in Attachment 3, "Modified Handling Requirements for the Protection of Certain Safeguards Information (SGI-M)."

The Order further requires, in part, that all licensees must ensure that all contractors whose employees may have access to safeguards information either adhere to the licensee's policies and procedures on safeguards information or develop, maintain, and implement their own acceptable policies and procedures, but the licensees remain responsible for the conduct of their contractors. Additionally, Attachment 3 requires, in part, that access to SGI-M by licensee employees, agents, or contractors must include a determination concerning the trustworthiness of individuals having access to the information.

Contrary to the above, from December 3, 2003, through April 2004, the licensee failed to ensure that its contractor, whose employees had access to safeguards information, either adhere to the licensee's policies and procedures on safeguards information or develop, maintain, and implement their own acceptable policies and procedures. Specifically, the licensee provided employees of its security contractor with access to safeguards information but failed to ensure that the contractor adhere to the licensee's policies and procedures on safeguards information or develop, maintain, and implement their own acceptable policies and procedures. Additionally, the licensee failed to make a determination concerning the trustworthiness of contractor employees that were given access to SGI-M information. Specifically, at least one employee of the licensee's security contractor was provided with documents that contained SGI-M but a trustworthiness determination of the individual had not been made.

This is a Severity Level III violation (Supplement III).

Pursuant to the provisions of 10 CFR 2.201, Sterigenics International, Inc., (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and

Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation: EA-06-035" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty proposed above, in accordance with NUREG/BR-0254 and by submitting to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, a statement indicating when and by what method payment was made, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation (EA-06-035)" and may: (1) deny the violations listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty, in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.C.2 of the Enforcement Policy should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234(c) of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, statement as to payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Cynthia A. Carpenter, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011.



Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

Dated this 18<sup>th</sup> day of September 2006

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